

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claim 1. (currently amended) A method for making composite active particles for pulmonary inhalation, the method comprising the step of jet milling active particles in the presence of particles of additive material so that the additive material coats the active particles.

Claim 2. (previously presented) A method as claimed in claim 1, wherein the additive material is selected from the group consisting of: an amino acid, a metal stearate and a phospholipid.

Claim 3. (previously presented) A method as claimed in claim 2, wherein the additive material is selected from the group consisting of: leucine, isoleucine, lysine, valine, methionine, phenylalanine, and a combination of any of the foregoing.

Claim 4. (previously presented) A method as claimed in claim 3, wherein the additive material comprises one of the following: leucine and L-leucine.

Claim 5. (original) A method as claimed in claim 2, wherein the additive material comprises magnesium stearate.

Claim 6. (original) A method as claimed in claim 2, wherein the additive material comprises lecithin.

Claim 7. (previously presented) A method as claimed in claim 1, wherein the step of jet milling is carried out at an inlet pressure of between 0.1 and 3 bar.

Claim 8. (previously presented) A method as claimed in claim 1, wherein the step of jet milling is carried out at an inlet pressure of between 3 and 12 bar.

Claim 9. (previously presented) A method as claimed in claim 1, wherein at least 90% by volume of the active particles are less than 20 μ m in diameter prior to the step of jet milling.

Claim 10. (previously presented) A method as claimed in claim 1, wherein at least 90% by volume of the additive particles are less than 20 μ m in diameter prior to the step of jet milling.

Claim 11. (previously presented) A method as claimed in claim 1, wherein the step of jet milling is carried out at temperatures below room temperature.

Claim 12. (previously presented) A method as claimed in claim 11, wherein the step of jet milling is carried out at a temperature below 10°C.

Claim 13. (previously presented) A method as claimed in claim 1, wherein the step of jet milling further comprises jet milling carrier particles with the active particles and the particles of additive material.

Claim 14. (original) A method as claimed in claim 13, wherein the carrier particles have a particle size of at least 20 μ m.

Claim 15. (previously presented) A method as claimed in claim 13, wherein the carrier particles have a particle size of less than 30 μ m.

Claim 16. (previously presented) A pharmaceutical composition comprising composite active particles prepared in accordance with the method as claimed in claim 1.

Claim 17. (previously presented) The pharmaceutical composition of claim 16, wherein said composition is for pulmonary inhalation.

Claim 18. (previously presented) The pharmaceutical composition of claim 16, wherein the additive material forms a coating on the surface of the composite particles.

Claim 19. (previously presented) The pharmaceutical composition of claim 18, wherein the coating is a discontinuous coating.

Claim 20. (previously presented) The pharmaceutical composition of claim 18, wherein the coating of additive material is not more than 1 μ m in thickness.

Claim 21. (previously presented) The pharmaceutical composition of claim 16, wherein said composite active particles have an MMAD of not more than 10 μ m.

Claim 22. (previously presented) The pharmaceutical composition of claim 21, wherein said composite active particles have an MMAD of not more than 5 μ m.

Claim 23. (previously presented) The pharmaceutical composition of claim 16, wherein at least 90% by weight of the composite active particles have a diameter of not more than 10 μ m.

Claim 24. (previously presented) The pharmaceutical composition of claim 23, wherein at least 90% by weight of the particles have a diameter of not more than 5 μ m.

Claims 25-26 (cancelled)

Claim 27. (previously presented) A composition as claimed in claim 16, wherein the composition is a dry powder composition.

Claim 28. (previously presented) A composition as claimed in claim ~~[27]~~16, wherein the composition further comprises carrier particles.

Claim 29. (previously presented) A composition as claimed in claim 16, wherein the composition has a FPF(ED) of at least 70%.

Claim 30. (previously presented) A composition as claimed in claim 29, wherein the FPF(ED) is at least 80%.

Claim 31. (previously presented) A composition as claimed in ~~in~~ claim 16, wherein the composition has a FPF(MD) of at least 60%.

Claim 32. (previously presented) A composition as claimed in claim 29, wherein the FPF(MD) is at least 70%.

Claim 33. (previously presented) A dry powder inhaler containing a composition as claimed in claim 16.

Claim 34. (canceled)

Claim 35. (previously presented) A method as claims in claim 1, wherein the step of jet milling active particles is carried out in the presence of particles of additive material and one of the following: air, compressible gas and fluid.

Claim 36 (previously presented) A method according to claim 11, wherein the step of jet milling is carried out at a temperature below 0°C.

Claim 37. (previously presented) A method as claimed in claim 13, wherein the carrier particles have a particle size of less than 20µm.

Claim 38. (previously presented) A method as claimed in claim 13, wherein the carrier particles have a particle size of less than 10 μ m.

Claim 39. (previously presented) A pharmaceutical composition as claimed in claim 21, wherein said composite active particles have an MMAD of not more than 1 μ m.

Claim 40. (previously presented) A pharmaceutical composition as claimed in claim 23, wherein at least 90% by weight of the particles have a diameter of not more than 1 μ m.

Claim 41. (previously presented) A composition as claimed in claim 29, wherein the FPF(ED) is at least 90%.

Claim 42. (previously presented) A composition as claimed in claim 29, wherein the FPF(MD) is at least 85%.